UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,669	11/27/2001	Ann-Kristin Karlsson	06275-160002	1605

7590 09/09/2002

JANIS K. FRASER
Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804

EXAMINER	
MAIER, LEIGH C	
ART UNIT	PAPER NUMBER
1623	7

DATE MAILED: 09/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/993,669	Applicant(s) Karlss n
	Examiner Leigh Maier	Art Unit 1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 12, 2002*

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *3, 4, 6, 8-12, 14, and 30-55* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *3, 4, 6, 8-12, 14, and 30-55* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Claims

Claims 3, 8, 10, 11, and 39 have been amended. Claims 49-55 have been added. Claims 3, 4, 6, 8-12, 14, 30, and 31-55 are pending. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any objection or rejection not specifically repeated has been withdrawn.

Claim Objections

Claims 10 and 11 are objected to as not being proper dependent claims, as set forth in the previous Office action. New claims 53 and 55 are likewise objected to.

Applicant's arguments filed June 12, 2002 have been fully considered but they are not persuasive.

Regarding claim 10, Applicant argues that claim 8 includes the transitional phrase "comprising" which is open ended, and the additive of claim 10 is present *in addition* to the dry, finely divided particles. The examiner agrees that the claim is open ended. However, the dependent claims must be embraced by the scope of the independent claim, and this claim requires a formulation comprising the powder in the form of *dry* particles. The powder, in combination with non-dry additives, would no longer be dry and would conflict with the

limitation of the claim. Claim 10 clearly contemplates a solution that is being rendered isotonic with an additive for this purpose. See line 3 of the claim.

Regarding claim 11, Applicant argues that a dry material has a volume that can be expressed in mL. In principle this is correct. However, one of ordinary skill, especially in view of the specification, (see page 10, lines 10-12) would understand this unit of measure to indicate a liquid, either a solution or suspension. By definition, a solution or suspension can not comprise *dry* particles. In a solution, the particles are dissolved, so they are no longer *particles*, much less dry. In a suspension, the particles are dispersed in a fluid, but not dissolved. By virtue of the contact with the fluid, the particles cannot be dry. In the arguments, Applicant has not unambiguously stated that the compositions contemplated are dry. The addition of new claims 53 and 54 supports the reading that Applicant contemplates compositions not limited to dry components.

Regarding claim 53, as discussed above, claim 8 requires a formulation comprising the powder in the form of *dry* particles. As discussed above, a suspension, required by claim 53, can not comprise *dry* particles.

Regarding claim 55, the claim depends from new claim 54 which is drawn to a suspension comprising sterilized, finely divided particles. Claim 55 requires that the particles be dry. As discussed above, particles in a suspension cannot be dry.

Claim Rejections - 35 U.S.C. § 102

Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by O'NEILL (US 3,962,430) as set forth in the previous Office action. Newly submitted claim 53 is likewise rejected.

Applicant's arguments filed June 12, 2002 have been fully considered but they are not persuasive.

Applicant argues that O'NEILL does not disclose a powder in the form of dry, finely divided particles, the dry particles being sterilized. This was also noted by the examiner in the Office action. However, the claims contemplate (or explicitly require, as in claim 53) a suspension, and the examiner maintains that when a sterile solution/suspension of a glucocorticosteroid is prepared and sterilized, it is indistinguishable from one prepared from a sterile, dry solid.

Claims 10 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by SAIDI et al (US 6,241,969) as set forth in the previous Office action.

Applicant's arguments filed June 12, 2002 have been fully considered but they are not persuasive.

Applicant argues that SAIDI does not disclose a powder in the form of dry, finely divided particles, the dry particles being sterilized. This was also noted by the examiner in the Office action. However, the claims contemplate formulations, including solutions, in which the particles

are not dry. The examiner maintains that when a sterile solution of a glucocorticosteroid is prepared and sterilized, it is indistinguishable from one prepared from a sterile, dry solid.

In traversing the rejections over O'NEILL and SAIDI, Applicant argues that these references do not disclose compositions comprising dry particles, but goes on to disregard this limitation in claiming compositions *precluding* dry particles.

Claim Rejections - 35 U.S.C. § 103

Claims 3, 4, 6, 8-10, 12, 14, 34-36, 39, 41, 42, and 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over JAKUPOVIC et al (WO 96/32095) in view of BUSSEY et al (J. Parenter. Sci. Tech., 1983), as set forth in the previous Office action. New claims 49-55 are also rejected.

Applicant's arguments filed June 12, 2002 have been fully considered but they are not persuasive.

Applicant states that JAKUPOVIC "merely teaches an inhalation compound which is dissolved in a solvent." The examiner respectfully disagrees with this characterization of the reference. As clearly indicated in the Office action, JAKUPOVIC teaches respirable dry particles. See paragraph bridging pages 3 and 4, and the paragraph immediately thereafter. JAKUPOVIC is merely silent regarding sterilization. BUSSEY teaches sterilization.

Applicant argues that BUSSEY "merely teaches bulk sterilization of corticosteroids by ^{60}Co irradiation." Exactly. BUSSEY teaches sterilization of corticosteroids. It is not clear what Applicant's point is in this statement: (1) This method is inappropriate for sterilization of "glucocorticosteroids" because it is concerned with "corticosteroids"; or (2) This method is inappropriate for sterilization of dry particles because it is directed toward "bulk sterilization." Regarding (1), according to the definition submitted by Applicant, "glucocorticosteroids" are a sub-set of "corticosteroids." Furthermore, one of the species (prednisolone) taught by BUSSEY is one contemplated by Applicant. See specification at page 4, line 20. Regarding (2), it is not clear how "bulk sterilization" precludes sterilization of dry particles in bulk.

Further regarding BUSSEY, Applicant notes that BUSSEY shows amounts of degradation. Table III shows about 1% or less degradation. However, the other 99+% is sterile. Finally, with no supporting evidence, applicant states that BUSSEY is "not concerned with producing a pharmaceutically acceptable powder." Given that in the Introduction, the reference discusses that the described study concerns sterilization of products produced by the *pharmaceutical* industry, one of ordinary skill would reasonably expect that this method is appropriate for sterilizing compounds for pharmaceutically acceptable formulations.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the

time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.d. 1392, 170 USPQ 209 (~~CCA~~ CCPA 1971).

Regarding claims 39, 41, 42, 45, 46, and new claims 49-52: Claim 39 recites a product-by-process. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. There does not appear to be any difference between a dry glucocorticosteroid sterilized by heating, as recited in the claims, and a dry glucocorticosteroid sterilized by irradiation or treatment by ethylene oxide.

This rejection was made in the previous Office action but not addressed by Applicant in the response.

Claims 3, 4, 6, 8-10, 12, 14, 32-37, 39-42, and 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over JAKUPOVIC et al (WO 96/32095) in view of BUSSEY et al (J. Parenter. Sci. Tech., 1983) and in further view of RADHAKRISHNAN et al (US 5,192,528), as set forth in the previous Office action. New claims 49-55 are also rejected.

Claims 3, 4, 6, 8-12, 14, 30, 31, 34-36, 38, 39, 41-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over JAKUPOVIC et al (WO 96/32095) in view of BUSSEY et al (J. Parenter. Sci. Tech., 1983) and in further view of SEQUIEIRA et al (US 5,837,699), as set forth in the previous Office action. New claims 49-55 are also rejected.

Applicant's arguments filed June 12, 2002 have been fully considered but they are not persuasive.

Applicant argues on the basis that JAKUPOVIC and BUSSEY do not teach or suggest "a pharmaceutically acceptable powder in the form of dry, finely divided particles, the dry particles being sterilized." This is addressed above.

Applicant further argues that neither RADHAKRISHNAN nor SEQUIEIRA teach or suggest "a pharmaceutically acceptable powder in the form of dry, finely divided particles, the dry particles being sterilized." The examiner agrees. RADHAKRISHNAN was used to teach particle size. SEQUIEIRA was used to teach the use of claimed glucocorticosteroids for allergic, inflammatory, and pulmonary diseases.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over RADHAKRISHNAN et al (US 5,192,528), as set forth in the previous Office action. New claims 53-55 are also rejected.

Applicant's arguments filed June 12, 2002 have been fully considered but they are not persuasive.

Again, Applicant argues that RADHAKRISHNAN does not teach or suggest "a pharmaceutically acceptable powder in the form of dry, finely divided particles, the dry particles being sterilized." Applicant has not addressed how a sterile suspension of the

glucocorticosteroid, prepared and subsequently sterilized, can be distinguished from one prepared from a sterile, dry solid.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Tuesday, Wednesday, or Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Johann Richter (703) 308-4532, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
September 5, 2002

KATHLEEN K. PONDA
PRIMARY EXAMINER